



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

SEP 28 2000

Mr. Michael Turanchik  
Director, Research & Development  
Medtox Diagnostics, Inc.  
1238 Anthony Road  
Burlington, North Carolina 27215

Re: K002776  
Trade Name: Profile® -II  
Regulatory Class: II  
Product Code: LCM, DKE, DIO, DJG, DKZ  
Dated: September 1, 2000  
Received: September 6, 2000

Dear Mr. Turanchik:

We have reviewed your Section 510(k) notification of intent to market ~~the device referenced~~ above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in ~~interstate commerce~~ prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

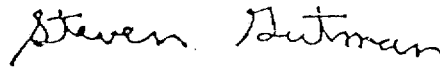
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K002776Device Name: Profile®-II

## Indications For Use:

The Profile®-II is a one-step immunochromatographic test for the rapid qualitative detection of Cannabinoids (THC), cocaine, opiates, amphetamines and phencyclidine (PCP) in human urine. The cutoffs of these drugs are at the following concentrations:

THC	Tetrahydrocannabinol	50 ng/mL
COC	Cocaine (Benzoylecgonine)	300 ng/mL
OPI	Opiates (Codeine/Morphine)	2000 ng/mL
AMP	Amphetamine	1000 ng/mL
PCP	Phencyclidine	25 ng/mL

This product is intended for use under medical supervision in hospitals, physician offices, health clinics and drug treatment/counseling centers. It is ~~not for over the~~ counter sale.

Profile®-II provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed ~~analytical result~~. Gas chromatography/mass spectrometry (GC/MS) is preferred confirmatory method. Clinical consideration and professional judgement should be applied to ~~any drug of~~ abuse test result.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE  
IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Carol C. Benson for Jean Cooper*  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K002776

Prescription Use ☒

OR

Over-The-Counter Use ☐